NATIONAL DAIRY COUNCIL®

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August 19, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Dear Sir/Madam,

We appreciate the opportunity to provide comments and suggestions regarding program priorities in the Center for Food Safety and Applied Nutrition (CFSAN) for use in developing the 2003 workplan [Docket No. 98N-0359]. As a major stakeholder in the FDA Foods Community, the NATIONAL DAIRY COUNCIL commends CFSAN for their steadfastness in completing their 2002 priority "A" goals. We also appreciate the agencies continued efforts to seek input from their stakeholders in order to arrive at a 2003 workplan that "does the most good for consumers".

The NATIONAL DAIRY COUNCIL ® is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The NATIONAL DAIRY COUNCIL ® has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NATIONAL DAIRY COUNCIL ® is recognized throughout the nation as a leader in nutrition education.

In February 1995 and again in June 2000, we sent letters to Dr. 's David Kessler and Jane Henney, respectively, who were then Commissioner's of the FDA, outlining our concerns about the rampant increase of calcium fortified foods in the marketplace. It is still apparent that many food manufacturers are fortifying their products with high levels of calcium as well as myriad of other nutrients to gain a market advantage without considering the full impact on the population as a whole.

Our concerns still stand:

- An increasingly large number of foods are being fortified with calcium – many at relatively high levels. This has raised concerns by experts that indiscriminant fortification of foods with high levels of calcium may increase the chance that population subgroups who are not at risk for calcium inadequacy will consume unacceptably high levels of calcium above the Tolerable Upper Intake of 2500 mg/d.

- Many calcium fortified foods in the marketplace are currently out of compliance with the 1980 FDA food fortification policy (21 CFR §104.20):

  - Many foods are fortified with calcium at levels much higher than 50 mg/100 kcals recommended by FDA (many $\geq$ 300 mg/serving).
  - Foods with low nutrient density, such as candy, water, juice drinks and snack foods are being fortified with calcium.

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- Foods fortified with high levels of calcium are target marketed to subgroups of the population that are at low risk of calcium inadequacy and who are most vulnerable to over consumption based on dietary patterns.
- Currently, it is not possible to evaluate the extent of calcium or other nutrient over consumption in the U.S. population because national nutrition surveys do not provide quantitative information about nutrients consumed from dietary supplements and fortified foods.

Our recommendation still stands:

- We believe that the current food fortification policy and guidelines set forth by FDA in 21 CFR §104.20 is a rationale approach to food fortification. However, we strongly encourage CFSAN to enforce these standards and guidelines to help prevent excessive nutrient intakes from fortified foods and dietary supplements.

We are not alone in our concerns:

- The American Dietetic Association report and official position on food fortification and dietary supplements (2001) states:
  - "Fortification of the food supply must be moderated to benefit people who need to increase their nutrient intakes without increasing the risk of excessive intake to others." And

Today, our concerns are even greater. Many foods such as calcium-fortified frozen waffles, rice, pasta, snack bars, juices of all kinds, water, candy and chewy confections have taken their place in the marketplace. According to New Product News, 150 calcium-enriched products were introduced in 1999; triple the amount that debuted in 1998.

This trend of fortification frenzy is showing little signs of letting up. Between 1999 and 2001, the number of calcium fortified products soared to 219 a 351% increase. Other nutrients increased as well, with a 500% increase in vitamin C and a 475% increase in iron fortified product (New Product News, 2002). According to a report in *Food Technology*, the percentage of consumers who are trying to include more fortified foods in their diet increased from 56% in 1997 to 66% in 1999. Currently, "Generation Xer's" (20-30 year olds) lead the pack of fortified food users (73%), followed by "Baby Boomers" (68%) and the more "Mature" (60%). Without clear standards and enforced guidelines that address the current market environment of indiscriminant calcium fortification, the risk of exceeding the UL of 2500 mg/d becomes a very real possibility for those consumers who are least likely to be calcium inadequate and who consume the most amount of food (i.e. teenage boys and men). Indeed, a recent epidemiological report indicated that the highest 10% of Finnish adult men receive on average 2315 mg calcium per day from diets that do not include fortified foodstuffs (Suojanen et al., 2002). Consumption of fortified foods would increase the calcium intake further to levels exceeding the tolerable upper intake level (2500 mg/d). These authors concluded that liberal addition of calcium to various foods could increase the calcium intake in the highest decile to levels with potentially untoward health effects.

Some well-known brands of cereal are fortified with exceptionally high levels of calcium – 60% and 100% of the RDI or 600 and 1,000 mg of calcium per 1-cup serving. A serving of these cereals with ½ cup of milk, provides either 750 or 1,100 mg of calcium. Experts indicate that a large single bolus of calcium will be less efficiently absorbed than divided doses throughout the day. Although the type of calcium chosen for fortification of cereals in question (calcium carbonate) has been extensively tested for its positive influence on

bone, the food matrix of cereals contains inhibitors to calcium absorption (Weaver, 1998). Inhibitors, such as phytic acid abundant in wheat bran, could reduce the absorption of calcium – both naturally present in the food or when added as a fortificant. Thus, consumers may be misled into thinking that one serving of cereal will supply their daily calcium requirement when it may not.

While we are concerned about over fortification, we are equally concerned with the misleading efforts of some food manufactures. Consumers, who are led to replace dairy foods with foods highly fortified with calcium, may get less absorbable calcium than they think, and miss out on an important source of several other nutrients. "As a food group, only dairy products contain significant quantities of calcium naturally," says Connie Weaver, PhD, in a recent review of food calcium fortification strategies. "If the dairy group is not consumed," Dr. Weaver continues, "other nutrients normally supplied in dairy products may be deficient. Low intakes of calcium have been associated with low intakes of magnesium, riboflavin, vitamin B6, vitamin B12 and thiamin."

From national survey data, the Food and Drug Administration estimates that 20-30% of young children (ages 1-8 yr) may exceed the UL for folic acid, because of the frequent use of fortified breakfast cereals, fortified grain products, and dietary supplements (Lewis et al., 1999). In a commentary in the May 11, 2000 issue of the New England Journal of Medicine, addressing folate fortification policy, warns against using the U.S. population "to conduct an uncontrolled, unmonitored experiment." However, this is exactly what occurs when there is not data to support the benefits or evaluate the possible risks of fortifying the food supply with a particular nutrient.

We reiterate our recommendations and urge CFSAN to build into their 2003 strategic plans a priority goal to enforce the current food fortification standards and guidelines as outlined in 21 CFR §104.20 to help prevent excessive nutrient intakes from fortified foods and dietary supplements. We believe this is needed to protect the consumer from unacceptably high nutrient intakes and from possible adverse health effects. Finally, we believe that this is one critical area where CFSAN "can do the most good for consumers".

Sincerely,

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References

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